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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,993	02/18/2005	Ljubomir Antoncic	LI/G-33039A	3941
1095	7590	08/18/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			FREISTEIN, ANDREW B	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/524,993	ANTONCIC ET AL.	
	Examiner	Art Unit	
	Andrew B. Freistein	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,31,33-37 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,31,33-37 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/18/05; 2/09/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 8/15/2006 has been entered. Claims 29, 31, 33-37 and 41-43 are pending. Claims 1-28, 30, 32, 38-40 and 44-50 were cancelled.

Priority

This application is a 371 of PCT/SI04/00001, filed 01/29/2004. Acknowledgement is made of Applicant's claim for foreign priority under 35 U.S.C. § 119(a)-(d), by Slovenia patent application P-200300026 filed on 01/30/2003; Slovenia patent application P-200300025 filed on 01/30/2003; Slovenia patent application P-200300145 filed on 06/12/2003; Slovenia patent application P-200300157 filed on 06/26/2003; and Slovenia patent application P-200300270 filed on 11/05/2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on 02/18/2005 and 02/09/2006, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

In a response filed 08/15/2006, Applicant elected Group I, claims 29, 31, 33-37 and 41-43 (without traverse).

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al., US 2004/0097568 A1.

Claims 29 and 31 of the instant invention is drawn to a potassium salt of losartan in crystal Form X characterized by a powder X-ray diffraction pattern with peaks at about 6.9, 13.8, 20.6, 24.0, 24.8, 28.7, and 29.2 ± 0.2 , depicted as Figure 31. Claims 33-36 are drawn to a potassium salt of losartan which is substantially pure and has desired particle sizes. Claims 41-43 are drawn to a pharmaceutical composition comprising the potassium salt of losartan of claim 29, wherein claims 42-43 are drawn to the tablet form.

Reddy et al. disclose losartan potassium Form III having the X-ray diffraction pattern having peaks at: 7.154, 13.911, 20.728, 24.904, 24.192, 28.908 and 29.474 ± 0.09 (see p. 3, paragraphs [0028] & [0029]). When the margin of error for instant application and the prior art are taken into account, all of the peaks of the instant application are anticipated by the prior art.

Further, the prior art discloses pharmaceutical formulations in solid form and specifically tablets (see p. 4, paragraphs [0033] & [0034]).

The prior art does not disclose the particle size and purity of the polymorph. Nevertheless, the purity and particle size are inherent properties and thus the instant claims are anticipated. Therefore, claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al., US 2004/0097568 A1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 31 and 35 claims a potassium salt of losartan in crystal form X characterized by 7 peaks in a powder X-ray diffraction pattern. The data provided in these claims is not sufficient to distinguish the claimed polymorph from the existing polymorphs.

According to Polymorphism in Pharmaceutical Solids:

The USP general chapter on x-ray diffraction states that identity is established if the scattering angles of the ten strongest reflections obtained for an analyte agree to within ± 0.20 degrees with that of the reference material, and if the relative intensities of these reflections do not vary by more than 20 percent (see Brittain, p. 236).

In this case, Claim 29, 31 and 35 shows data that does not meet the standard practice and it fails to properly characterize the claimed polymorph.

Secondly, an additional limitation such as the melting point of the claimed polymorph should be inserted into the claims in order to properly distinguish this claimed product over the prior art. The current claim fails to properly identify this product over the prior art.

Telephone Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626


For Joseph K. M^cKane
Supervisory Patent Examiner, AU 1626
Date: August 16, 2006